

Appendix A – Compilation of Judicial Admissions

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122	Collectively, Purdue, Actavis, Janssen, Endo, Cephalon, Mallinckrodt, KVK Tech and Amneal Pharmaceuticals are referred to as “ Manufacturer Defendants ” and are also included within the definition of “ Marketing Defendants. ”
259	Defendants AmerisourceBergen, Cardinal, McKesson, H.D. Smith, CVS, Rite Aid, Walgreens, Kroger, and Wal-Mart are collectively referred to herein as “ Distributor Defendants. ”
260	As set forth below, Defendants CVS, Rite Aid, Walgreens, Kroger, and Wal-Mart are also collectively referred to as National Pharmacies.
298	Collectively, Defendants Express Scripts, CVS Caremark, and Optum Rx are referred to as the “ PBM Defendants. ”
313	This drug crisis began with a corporate business plan. It started with a decision by Purdue and the Sackler Defendants (collectively, “Purdue Entities”), to promote opioids deceptively and illegally in order to significantly increase sales and generate billions of dollars in revenue for Purdue’s private owners, the Sackler family.
314	Purdue’s strategies were quickly joined by other manufacturers, including Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.; Janssen Pharmaceuticals, Inc.; Ortho- McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Johnson & Johnson; Noramco, Inc.; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Mallinckrodt PLC; Mallinckrodt LLC; SpecGx LLC, Amneal, and KVK Tech (collectively the “Marketing Defendants”).
315	Marketing Defendants manufacture, market, sell, and distribute branded and/or generic prescription opioid pain medications. Some of the relevant brand-name drugs include OxyContin, Butrans, Hysingla ER, Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydene, Nucynta/Nucynta ER, Duragesic, Exalgo, and Xartemis XR. The Marketing Defendants used misrepresentations regarding the risks and benefits of opioids to enable the widespread prescribing of opioids for common, chronic pain conditions like low back pain, arthritis, and headaches.
359	Purdue created a market for the use of opioids for a range of common aches and pains by misrepresenting the risks and benefits of its opioids, but it was far from alone. The other Marketing Defendants—already manufacturers of prescription opioids—positioned themselves to take advantage of the opportunity Purdue created, developing both branded and generic opioids to compete with

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	OxyContin, while, together with Purdue and each other, misrepresenting the safety and efficacy of their products. These misrepresentations are described in greater detail below.
372	Until the mid-1990s, opioids were widely thought to be too addictive for use for chronic pain conditions, which would require long-term use of the drugs at increasingly high doses. For these conditions, the risks of addiction and other side effects outweighed any benefit from the drugs. Over the last two decades, Marketing Defendants turned that consensus on its head by designing and implementing a sophisticated and deceptive market strategy that, among other things, falsely denied the risk of addiction and overstated the benefits of using opioids long-term.
373	Lacking legitimate scientific research to support their claims, Marketing Defendants turned to the marketing techniques first pioneered by Arthur Sackler to create a series of misperceptions in the medical community and ultimately reverse the long-settled understanding of the relative risks and benefits of opioids.
374	Through marketing that was as pervasive as it was deceptive, Marketing Defendants convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven. Purdue, for example, promoted the concept that pain was undertreated, that opioids could not be abused, that the rate of addiction to opioids was less than 1%, that “old views” of opioid addiction were untrue, and that “appropriate patients” would not become addicted.
375	The result was that by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. Marketing Defendants not only marketed opioids for chronic pain conditions, but also targeted primary care physicians (along with nurse practitioners and physician assistants), who were most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate Marketing Defendants’ marketing claims.
376	Marketing Defendants’ deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, which created an even broader cohort of patients who expected and received opioids. This laid the groundwork for today’s epidemic of opioid addiction, injury, and death.
378	The marketing scheme to increase opioid prescriptions centered around nine categories of misrepresentations, which are discussed in detail below. The Marketing Defendants disseminated these misrepresentations through various channels, including through advertising, sales representatives, purportedly independent organizations these defendants funded and controlled, “Front Groups,” so-called industry “Key Opinion Leaders,” and Continuing Medical

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	Education (“CME”) programs discussed subsequently below.
379	Marketing Defendants spent hundreds of millions of dollars on promotional activities and materials, including advertising, and websites that falsely denied or trivialized the risk of addiction and overstated the benefits of opioids. They also relied upon unsupported and misleading information derived from seminars, treatment guidelines, and other publications and programs by patient advocacy groups, professional associations, and physicians that seemed independent and therefore credible, but were actually funded and controlled by Marketing Defendants.
384	<p>The Marketing Defendants’ misrepresentations generally fall into the following nine categories:</p> <ol style="list-style-type: none"> 1. The risk of addiction from chronic opioid therapy is low 2. Signs of addictive behavior are “pseudoaddiction,” requiring more opioids 3. To the extent there is a risk of addiction, it can be easily identified and managed 4. Opioid withdrawal can be avoided by tapering 5. Long-term opioid use improves functioning 6. Opioid doses can be increased without limit or greater risks 7. Alternative forms of pain relief pose greater risks than opioids 8. OxyContin provides twelve hours of pain relief 9. New formulations of certain opioids successfully deter abuse
385	Each of these propositions was false. The Marketing Defendants knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.
388	To convince prescribers and patients that opioids are safe, Marketing Defendants deceptively represented that the risk of abuse and addiction is modest and manageable and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted, (2) patients at greatest risk of addiction could be identified, and (3) all other patients could safely be prescribed opioids.
389	Marketing Defendants undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to high-risk patients. These Defendants also minimized the difficulty of withdrawal in their marketing material and promotional programs. For example, a 2011 non-credit educational program sponsored by Endo, entitled Persistent Pain in the Older Adult, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient’s opioid dose over ten days. However, this claim is at odds with the experience of patients addicted to opioids.

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	Most patients who are dependent upon or addicted to opioids will experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.
441	Marketing Defendants covered up the occurrence of addiction by attributing it to a made-up condition they called “pseudoaddiction.” Signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel.
444	<i>Responsible Opioid Prescribing</i> was sponsored by Purdue, Endo, and Teva. The FSMB website described the book as the “leading continuing medical education (CME) activity for prescribers of opioid medications.” In all, more than 163,000 copies of <i>Responsible Opioid Prescribing</i> were distributed nationally.
450	Marketing Defendants falsely instructed prescribers and patients that screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies actually work to mitigate addiction risk. By using screening tools, these Defendants advised doctors that they could identify patients likely to become addicted and safely prescribe to everyone else.
460	Nevertheless, upon information and belief, Marketing Defendants touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.
461	In addition, two prominent professional medical membership organizations, the American Pain Society (“APS”) and the American Academy of Pain Medicine (“AAPM”), each received substantial funding from Marketing Defendants. According to a letter from U.S. Senate Committee on Finance Ranking Member Ron Wyden to Secretary Thomas Price of the U.S. Department of Health & Human Services, as recently as May 2017, the Corporate Council of AAPM included Endo, Janssen, Purdue and Teva, along with several other pharmaceutical drug companies. Upon information and belief, Marketing Defendants exercised considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, <i>The Use of Opioids for the Treatment of Chronic Pain</i> , which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co- author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. KOL Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM’s website until 2011 and was only removed from AAPM’s website after a doctor

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	complained.
463	AAPM and APS issued treatment guidelines in 2009 (“AAPM/APS Guidelines”) which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Marketing Defendants in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Purdue, eight from Teva, nine from Janssen, and ten from Endo.
464	The AAPM/APS Guidelines promote opioids as “safe and effective” for treating chronic pain. The panel made “strong recommendations” despite “low quality of evidence” and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.
466	The AAPM/APS Guidelines are still available online, were reprinted in the <i>Journal of Pain</i> , and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature. These Guidelines were available to Huntington prescribers.
477	Marketing Defendants also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs.
478	Marketing Defendants’ materials that, upon information and belief, were distributed or made available in the City, reinforced this message. The 2011 publication <i>A Policymaker’s Guide</i> falsely claimed that “multiple clinical studies have shown that opioids are effective in improving” “[d]aily function” and “[o]verall health-related quality of life for people with chronic pain.” A series of medical journal advertisements for OxyContin in 2012 presented “Pain Vignettes”—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a “writer with osteoarthritis of the hands” and implied that OxyContin would help him work more effectively. Similarly, starting in at least May of 2011, Endo distributed and made available on its website, <i>opana.com</i> , a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

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479	<p>Additional illustrative examples are described below:</p> <ul style="list-style-type: none"> a. Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which states as “a fact” that “opioids may make it easier for people to live normally.” The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that “[u]sed properly, opioid medications can make it possible for people with chronic pain to ‘return to normal.’” b. Responsible Opioid Prescribing (2007), sponsored and distributed by Teva, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients’ function. The book remains for sale online. c. Purdue and Teva sponsored APF’s Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids “give [pain patients] a quality of life we deserve.” The guide was available online until APF shut its doors in May 2012. d. Endo’s NIPC website painknowledge.com claimed in 2009 that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” Elsewhere, the website touted improved quality of life (as well as “improved function”) as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC’s intent to make claims of functional improvement, and Endo closely tracked visits to the site. e. Endo was the sole sponsor, through NIPC, of a series of CMEs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.” The CME was disseminated via webcast.
480	<p>Mallinckrodt followed suit, stating on its website, in a section on “responsible use” of opioids, claims that “[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society.”</p>
481	<p>Likewise, Marketing Defendants’ claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients’ pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients’ health and pain. Increasing the duration</p>

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	of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.
485	In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and death, Marketing Defendants routinely ignored other risks, such as hyperalgesia, a “known serious risk associated with chronic opioid analgesic therapy,” in which the patient becomes more sensitive to pain over time; hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (conditions that often accompany chronic pain symptoms).
489	Marketing Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of NSAIDs. These Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (<i>See e.g., Case Challenges in Pain Management: Opioid Therapy for Chronic Pain</i> (Endo) [describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids]; <i>Finding Relief: Pain Management for Older Adults</i> (Janssen) [NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary “upset stomach or sleepiness” and constipation].)
491	Again, Marketing Defendants’ misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%. The CDC reports that the quantity of opioids dispensed per capita tripled from 1999 to 2015.
492	Marketing Defendants falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. These Defendants needed to generate a comfort level among doctors to ensure the doctors maintained patients on the drugs even at the high doses that became necessary. Further, as described in more detail below, Purdue encouraged doctors to prescribe higher doses, rather than prescribe OxyContin more frequently than twice-a-day—despite knowing that OxyContin frequently did not provide 12 hours of relief.
502	To convince prescribers and patients to use OxyContin, Purdue misleadingly

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	promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch.
511	Rather than take the widespread abuse and addiction to opioids as reason to cease their untruthful marketing claims and efforts, Defendants Purdue and Endo seized them as a market opportunity. These companies oversold their abuse-deterrent formulations ("ADF") as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids. Purdue's and Endo's false and misleading marketing of the benefits of its ADF opioids preserved and expanded their sales and influenced prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids—thereby prolonging the opioid epidemic in the City.
537	In sum, each of the nine categories of misrepresentations discussed above regarding the use of opioids to treat chronic pain was not supported by, or was contrary to, the scientific evidence. In addition, the misrepresentations and omissions set forth above and elsewhere in this Complaint are misleading and contrary to the Marketing Defendants' products' labels.
538	The Marketing Defendants' false marketing campaign not only targeted the medical community who had to treat chronic pain, but also patients who experience chronic pain.
539	The Marketing Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) "Front Groups" with the appearance of independence from the Marketing Defendants; (2) so-called "key opinion leaders" ("KOLs"), that is, doctors who were paid by the Marketing Defendants to promote their pro-opioid message; (3) CME programs controlled and/or funded by the Marketing Defendants; (4) branded advertising; (5) unbranded advertising; (6) publications; direct, targeted communications with prescribers by sales representatives or "detailers"; and speakers bureaus and programs.
542	The Marketing Defendants also "made substantial payments to individual group executives, staff members, board members, and advisory board members" affiliated with the Front Groups subject to the Senate Committee's study.
545	The most prominent of the Front Groups was the American Pain Foundation ("APF"). While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from defendants Purdue, Endo, Janssen and Cephalon. APF received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon,

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	Endo, and others to avoid using its line of credit. Endo was APF's largest donor and provided more than half of its \$10 million in funding from 2007 to 2012.
562	The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the <i>Journal of Pain</i> , have been cited hundreds of times in academic literature, were disseminated during the relevant period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Marketing Defendants promoted opioids, whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."
563	The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain.
564	The Marketing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines or their financial backing of the authors of these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled <i>The Role of Opana ER in the Management of Moderate to Severe Chronic Pain</i> relies on the AAPM/APS Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.
568	A 2004 iteration of the 1998 Guidelines and the 2007 book, <i>Responsible Opioid Prescribing</i> , also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in the City of Huntington.
569	FSMB's 2007 publication <i>Responsible Opioid Prescribing</i> was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. The publication also received support from the American Pain Foundation and the American Academy of Pain Medicine. The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of <i>Responsible Opioid Prescribing</i> were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as "the leading continuing medical education (CME) activity for prescribers of opioid medications." This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient..

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570	<p>The Marketing Defendants relied on the 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.</p>
579	<p>The U.S. Pain Foundation ("USPF") was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The USPF was one of the largest recipients of contributions from the Marketing Defendants, collecting nearly \$3 million in payments between 2012 and 2015 alone. The USPF was also a critical component of the Marketing Defendants' lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertises its ties to the Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (<i>i.e.</i>, Janssen), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members. Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.</p>
580	<p>The American Geriatrics Society ("AGS") was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. AGS was a large recipient of contributions from the Marketing Defendants, including Endo, Purdue and Janssen. AGS contracted with Purdue, Endo and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (<i>The Management of Persistent Pain in Older Persons</i>, hereinafter "2002 AGS Guidelines") and 2009 (Pharmacological Management of Persistent Pain in Older Persons, hereinafter "2009 AGS Guidelines"). According to news reports, AGS has received at least \$344,000 in funding from opioid manufacturers since 2009. AGS's complicity in the common purpose with the Marketing Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive-up front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.</p>
581	<p>The 2009 AGS Guidelines recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy." The panel made "strong recommendations" in this regard despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. These Guidelines further recommended that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." These recommendations are not supported by any study or other reliable</p>

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	scientific evidence. Nevertheless, they have been cited over 1,833 times in Google Scholar (which allows users to search scholarly publications that would be have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.
582	Representatives of the Marketing Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.
583	Members of AGS Board of Directors were doctors who were on the Marketing Defendants' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs also served in leadership positions within the AGS.
584	To falsely promote their opioids, the Marketing Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by the Marketing Defendants for their supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Marketing Defendants' well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception science and legitimate medical professionals favored the wider and broader use of opioids. These doctors include Dr. Russell Portenoy and Dr. Lynn Webster, as set forth in this section, as well as Dr. Perry Fine and Dr. Scott Fishman, as set forth in further below.
585	Although these KOLs were funded by the Marketing Defendants, the KOLs were used extensively to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.
586	As the Marketing Defendants' false marketing scheme picked up steam, these pro- opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs.
587	Through use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Marketing Defendants were able to exert control of each of these modalities through which doctors receive their information.
590	Once the Marketing Defendants identified and funded KOLs and those KOLs

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	began to publish “scientific” papers supporting the Marketing Defendants’ false position that opioids were safe and effective for treatment of chronic pain, the Marketing Defendants poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescription of opioids for chronic pain. The Marketing Defendants cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be well-received by the medical community. By contrast, the Marketing Defendants did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.
591	In their promotion of the use of opioids to treat chronic pain, the Marketing Defendants’ KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Marketing Defendants.
613	In 2007, Dr. Fishman authored a physician’s guide on the use of opioids to treat chronic pain titled Responsible Opioid Prescribing, which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.
618	One way the Marketing Defendants aggressively distributed their false message was through thousands of Continuing Medical Education courses (“CMEs”).
619	A CME is a professional education program provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations’ conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians’ medical expertise, they can be especially influential with doctors.
621	The Marketing Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.
625	<i>Responsible Opioid Prescribing</i> was sponsored by Purdue, Endo and Teva. The FSMB website described it as the “leading continuing medical education (CME) activity for prescribers of opioid medications.” Endo sales representatives

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	distributed copies of <i>Responsible Opioid Prescribing</i> with a special introductory letter from Dr. Scott Fishman.
626	In all, more than 163,000 copies of <i>Responsible Opioid Prescribing</i> were distributed nationally.
629	By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the Marketing Defendants could expect instructors to deliver messages favorable to them, as these organizations were dependent on the Marketing Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Marketing Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and the Marketing Defendants both measured the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.
630	The Marketing Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Marketing Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the <i>Journal of Pain</i> and <i>Clinical Journal of Pain</i> , to journals with wider medical audiences, such as the <i>Journal of the American Medical Association</i> . The Marketing Defendants collectively spent more than \$14 million on the medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.
631	The Marketing Defendants also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient specifically requests it. They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved. Endo's research, for example, also found that such communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. The Marketing Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and support" materials in the form of pamphlets, videos, or other publications that patients could view in their physician's office.
632	The Marketing Defendants also aggressively promoted opioids through "unbranded advertising" to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as "disease awareness"—encouraging consumers to "talk to your doctor" about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product's limits and risks. In contrast, a pharmaceutical company's "branded"

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	advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA Guidance on pharmaceutical advertising refers to as “fair balance.” Branded advertising is also subject to FDA review for consistency with the drug’s FDA-approved label. Through unbranded materials, the Marketing Defendants expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.
634	The Marketing Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.
635	To accomplish their goal, the Marketing Defendants—sometimes through third-party consultants and/or Front Groups—commissioned, edited, and arranged for the placement of favorable articles in academic journals.
637	The Marketing Defendants made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Marketing Defendants knew that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The Marketing Defendants also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence.
638	The Marketing Defendants published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy.
641	Each Marketing Defendant promoted opioids through sales representatives (also called “detailers”) and, upon information and belief, small group speaker programs to reach out to individual prescribers. By establishing close relationships with doctors, the Marketing Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers’ concerns about prescribing opioids for chronic pain.
643	Marketing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Marketing Defendants spent \$166 million on detailing branded opioids to doctors. This amount is twice as much as Marketing Defendants spent on detailing in 2000. The amount includes \$108

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	million spent by Purdue, \$34 million by Janssen, \$13 million by Teva, and \$10 million by Endo.
650	In addition to making sales calls, Marketers' detailers also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Marketing Defendants. These speaker programs and associated speaker trainings serve three purposes: they provide an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; to qualify to be selected a forum in which to further market to the speaker himself or herself; and an opportunity to market to the speaker's peers. The Marketing Defendants grade their speakers, and future opportunities are based on speaking performance, post-program sales, and product usage. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating on speakers' bureaus, providing consulting services, and other services.
651	The Marketing Defendants specifically targeted their marketing at two vulnerable populations—the elderly and veterans.
653	The Marketing Defendants promoted the notion—without adequate scientific foundation—that the elderly are particularly unlikely to become addicted to opioids. The AGS 2009 Guidelines, for example, which Purdue, Endo, and Janssen publicized, described the risk of addiction as “ <i>exceedingly low</i> in older patients with no current or past history of substance abuse.” (emphasis added). As another example, an Endo-sponsored CME put on by NIPC, <i>Persistent Pain in the Older Adult</i> , taught that prescribing opioids to older patients carried “possibly less potential for abuse than in younger patients.” Contrary to these assertions, however, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.
660	The Marketing Defendants necessarily expected a return on the enormous investment they made in their deceptive marketing scheme, and worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.
1202	As set forth herein, the Marketing Defendants deliberately worked through Front Groups purporting to be patient advocacy and professional organizations, through public relations companies hired to work with the Front Groups and through paid KOLs to secretly control messaging, influence prescribing practices and drive sales. The Marketing Defendants concealed their role in shaping, editing, and approving the content of prescribing guidelines, informational brochures, KOL presentations and other false and misleading materials addressing pain management and opioids that were widely disseminated to regulators, prescribers

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	<p>and the public at large. They concealed the addictive nature and dangers associated with opioid use and denied blame for the epidemic attributing it instead solely to abuse and inappropriate prescribing. They manipulated scientific literature and promotional materials to make it appear that misleading statements about the risks, safety and superiority of opioids were actually accurate, truthful, and supported by substantial scientific evidence. Through their public statements, omissions, marketing, and advertising, the Marketing Defendants' deceptions deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.</p>
1205	<p>The Marketing Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State and in Plaintiff's community deceived the medical community, consumers, the State, and Plaintiff's community.</p>